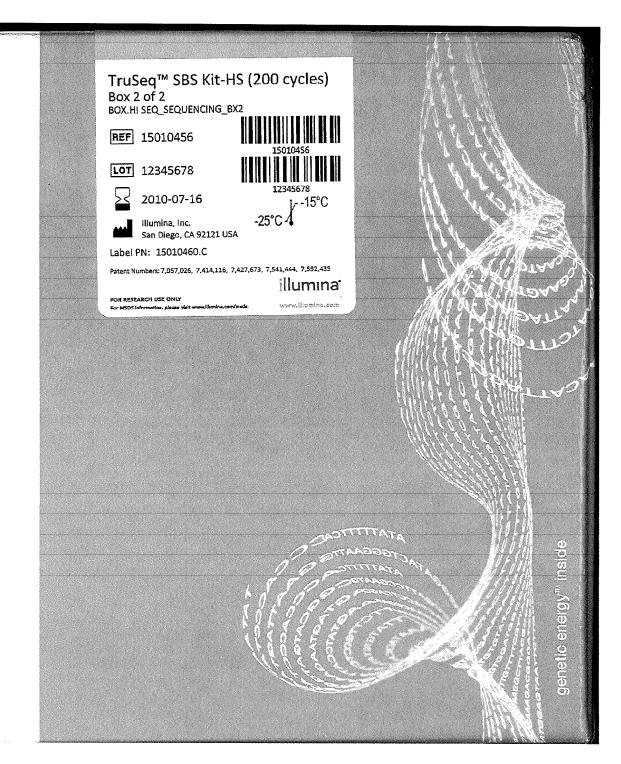
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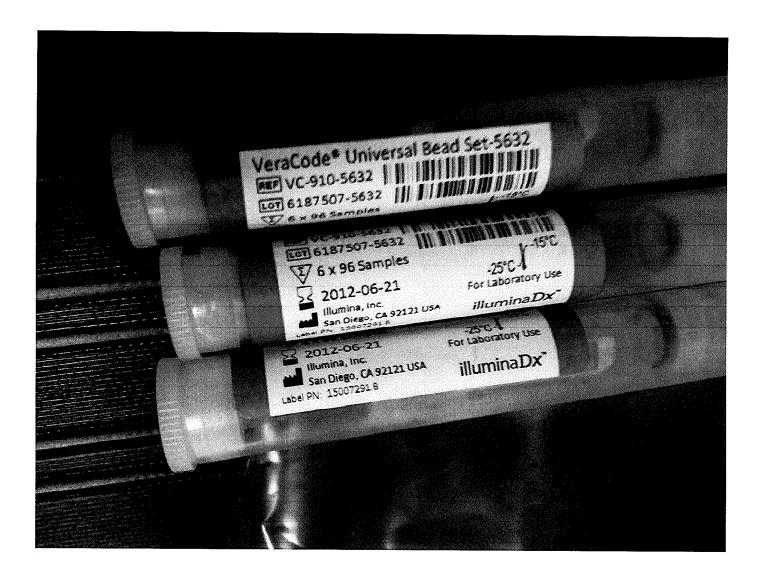
ESTTA637669 11/07/2014

Filing date:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91194218
Party	Plaintiff Illumina, Inc.
Correspondence Address	SUSAN M NATLAND KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN ST, 14TH FL IRVINE, CA 92614 UNITED STATES efiling@knobbe.com
Submission	Plaintiff's Notice of Reliance
Filer's Name	Brian C. Horne
Filer's e-mail	efiling@knobbe.com
Signature	/Brian C. Horne/
Date	11/07/2014
Attachments	Exhibit 323.pdf(3403008 bytes ) Exhibit 324.pdf(1424188 bytes ) Exhibit 325.pdf(2559790 bytes ) Exhibit 326.pdf(215099 bytes )





Whole-Genome DASL® HT DAP- 24 Sample BAG.DAP WG-DASL HT,HT12,v4,24

REF

15014439

LOT

12345678

Use in Pre-PCR Area Only



YYYY-MM-DD



Illumina, Inc.

San Diego, CA 92121

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Whole-Genome DASL® Assay Kit (96-Sample) BOX.WG-DASL w/UDG, PRE.1 MCS3, 96

REF 15004150

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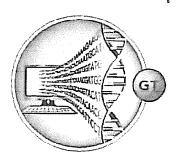
# GenomeStudio™ Genotyping Module v1.0 Application & Documentation

Part # 11319324

#### CONTENTS

- GenomeStudio Framework Application
- GenomeStudio
   Framework Documentation
- GenomeStudio Genotyping Module Application
- GenomeStudio Genotyping Module Documentation

ILLUMINA PROPRIETARY



illumina<sup>,</sup>

# Illumina® FastTrack Genotyping Services

Experience personalized service, industry-leading data quality, and guaranteed turnaround time with Illumina's FastTrack Genotyping Services for a wide range of SNP genotyping projects.

"Overall, our experience working with Illumina has been simply outstanding. The scientific and service staff of this organization are highly talented and committed individuals... The staff of Illumina went well beyond the normal service requirement in order to maximize information yield on these samples."

—PETER K. GREGERSON, M.D., Center Head, The Robert S. Boas Center for Genomics and Human Genetics

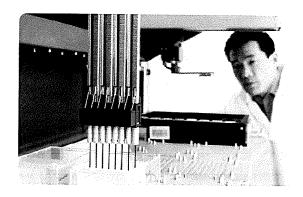
At Illumina, we work collaboratively with you to achieve your research objectives. Using Illumina's cutting-edge SNP genotyping technology, our in-house geneticists have consistently provided on-time, reliable genotyping services to academic and pharmaceutical customers since 2002. In collaboration with our customers, we have provided data for the study of many diseases through services projects, from various cancers to diabetes and schizophrenia. Using Illumina's FastTrack Services gives you the same competitive advantages as our installed base of customers: the ability to conduct whole-genome association studies, DNA copy number studies, linkage analysis, and fine mapping studies in a timely fashion at a reasonable cost.

In addition to the benefits you can realize by outsourcing your discovery efforts, you will also appreciate the professional design assistance and collaborative approach Illumina has proudly delivered since program inception. We highly value the quality outcome of your projects as much as your experience working with us.

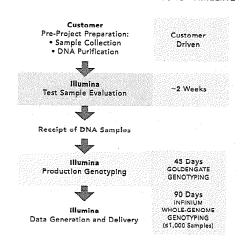


#### KEY HIGHLIGHTS OF PAST PERFORMANCE

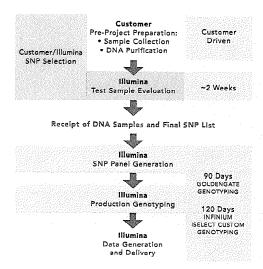
- Infinium® Service Projects:
   Sample Success Rate: 99.5%
   Call Rate: 99.89%
- GoldenGate® Service Projects: DNA Success Rate: 97.6% Call Rate: 99.75%



#### STANDARD PANEL GENOTYPING PROJECT TIMELINE



#### CUSTOM PANEL GENOTYPING PROJECT TIMELINE



#### PERSONALIZED SERVICE WITH DEDICATED EXPERTS

- An expert molecular geneticist project manager assigned to each project
- Project completion and success ensured with guaranteed fast delivery
- Intensive customer engagement with proven process flow driven by best practices
- Each project dataset reviewed and QC'd by the services group
- Every sample and every SNP locus assigned a quality score
- Streamlined custom SNP selection from an up-todate database of >1 million validated SNP markers
- Final annotated SNP lists specified with expected assay conversion rates

#### RELIABLE, PROVEN, FAST, AND ROBUST PROCESS

- Over 200 projects between 2002 and 2006, all delivered on time
- Guaranteed delivery date, with average study turnaround time <90 days
- Over 200,000 DNA samples genotyped, with nearly 100% success
- World-class Illumina BeadLab environment capable of generating over 75 million genotypes per day
- Expertise with large datasets—over 1 billion genotypes delivered for a single customer project
- Fully integrated custom Laboratory Information Management System (LIMS) tracking from sample input to data output and analysis
- Barcoded plates sent to customers to ensure accurate sample tracking
- Streamlined process for safe and secure dry ice sample shipment

#### INDUSTRY-LEADING DATA QUALITY

- Consistently impressive results from bestperforming genotyping products, quality-driven processes, and professional expertise
- · Maximal information value at every locus
- Illumina control samples included on every sample plate for extensive real-time QC and data review in LIMS environment
- Low sample input requirements

#### COMPREHENSIVE STUDY TYPES

- Industry's most flexible and comprehensive portfolio with Infinium and GoldenGate assays
- Standard and custom content
- Whole-genome and fine mapping studies
- Scalable multiplex levels—from 384 custom SNPs to 1 million standard SNPs per assay
- Wide sample size range—from 300 to several thousand
- Tag SNP selection available for any combination of the four HapMap populations
- All organisms supported; extensive experience with organisms such as human, cow, pig, chicken, mouse, dog, and corn
- Seamless transition to follow-on projects—from
   Infinium Whole-Genome Genotyping to iSelect Custom
   Genotyping, and then to targeted panels with Custom
   GoldenGate Genotyping—all with the same trusted
   team, quality data, and LIMS-driven process

#### SUMMARY

Take advantage of Illumina's full menu of FastTrack Genotyping Services. Our highly experienced FastTrack Project Managers are committed to working collaboratively with you from beginning to end, to ensure the highest quality data and fast turnaround. Enjoy the benefits of innovative technologies and personalized service from the genotyping market leader.

### INFINIUM WHOLE-GENOME GENOTYPING PAST PERFORMANCE\*

(Based on all contracts between January and September 2006 >11,500 BeadChips and 3.5 billion genotypes)

Infinium Service Projects	Average
Sample Success Rate	99.47%
Locus Success Rate	99.11%
Call Rate	99.89%
Reproducibility	99.99%
Heritability (Trios)	99.98%

<sup>\*</sup> Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

#### GOLDENGATE PAST PERFORMANCE\*

Based on all contracts between January 2005 and June 2006 (>150,000 individual DNA samples from 100 projects)

GoldenGate Service Projects	Average
Custom Assay Development Success - Human only - All species	92.8% 91.2%
DNA Success Rate	97.6%
Call Rate	99.75%
Reproducibility	>99.99%
Heritability	>99.99%

<sup>\*</sup> Performance for individual studies varies and depends on the DNA quality of the samples submitted and the quality of the SNPs selected

## NUMBER OF LOCI ASSAYED AND TURNAROUND TIME REQUIRED FOR FASTTRACK GENOTYPING SERVICES TO PROCESS STANDARD AND CUSTOM PANELS

Standard Panels	Number of Loci	Guaranteed Turnaround Time
GoldenGate Genotyping	~30~6000	45 days1
Infinium Whole-Genome Genotyping	300,000-1,000,000	90 days <sup>1, 2</sup>
Custom Panels		
Custom GoldenGate Genotyping	384-8,000+	90 days³
Infinium iSelect™ Custom Genotyping	7,600-60,800	120 days³
Infinium Semi-Custom HumanHap300-Duo+ Genotyping	7,600-60,8004	120 days²,³
Infinium Semi-Custom HumanHap550+ Genotyping	7,600-121,600 <sup>s</sup>	120 days <sup>2,3</sup>
<sup>1</sup> From DNA sample submission <sup>2</sup> For up to 1,000 samples <sup>3</sup> From date of final SNP list and DNA sample submission		
<sup>4</sup> Add 7,600–60,800 custom loci to standard 300,000 loci per sample <sup>3</sup> Add 7,600–121,600 custom loci to standard 550,000 loci		

ORDERING INFORMATION

#### FASTTRACK GENOTYPING SERVICES STANDARD PANEL PROJECTS

CATALOG #	PRODUCT	Number	DNA Required	Volume Required
		ef Leci	per Sample (µg)	per Sample (µl)
	Infinium Whole-Genome Genotyping			44
	Standard Panel Service Project			
FT-20-101	HumanHap300-Duo Genotyping BeadChip	>300,000	3	60
FT-20-102	HumanHap240S-Duo Genotyping BeadChip	>240,000	3	60
FT-20-104	HumanHap550 Genotyping BeadChip	>550,000	3	60
FT-20-105	HumanHap650Y Genotyping BeadChip	>650,000	3	60
FT-20-106	HumanHap450S DNA Analysis BeadChip	>450,000	3	60
FT-20-107	Human1M DNA Analysis BeadChip	>1,000,000	3	60
FT-20-108	HumanCNV370-Duo DNA Analysis BeadChip	>370,000	3	60
FT-20-111	HumanLinkage-12 DNA Analysis BeadChip	>6,000	1.5	30
FT-20-1094	BovineSNP50 Genotyping BeadChip	>50,000	1.5	30
FT-20-110°	CanineSNP20 Genotyping BeadChip	>20,000	1.5	30
FT-20-113 <sup>6</sup>	CVDSNP60 Genotyping BeadChip	>60,000	1.5	30
FT-10-101	GoldenGate Genotyping Standard			. <del></del>
	Panel Service Project			
	Linkage V Panel	6,056	4	80
	Mouse LD Linkage	377	2	40
	Mouse MD Linkage	1,449	2	40
	MHC Panel Set	2,360	4	80
	MHC Mapping Panel	1,293	2	40
	MHC Exon-Centric Panel	1,228	2	40
	Cancer SNP Panel	1,421	2	40

<sup>&</sup>lt;sup>6</sup>These products are currently available for ordering, but will not be in use until late 2007

#### FASTTRACK GENOTYPING SERVICES CUSTOM PANEL PROJECTS

CATALOG #	PRODUCT	Number of Loci	DNA Required per Sample (µg)	Volume Required per Sample (µl)
FT-15-101	Custom GoldenGate Genotyping Project	up to 1,536 1,632–4,608 4,704–9,216	2 4 6	40 80 120
FT-25-101	Infinium iSelect Custom Genotyping Project	7,600–60,800	1.5	30
FT-25-102	Infinum Semi-Custom HumanHap300-Duo+ Genotyping Project	7,600–60,800 <sup>7</sup>	3	60 60
FT-25-103	Infinium Semi-Custom HumanHap550+ Genotyping Project	7,600–121,600	3	60

<sup>&</sup>lt;sup>7</sup>Add 7,600–60,800 custom loci to the standard 300,000 loci per sample on the HumanHap300-Duo Genotyping BeadChip <sup>8</sup>Add 7,600–121,600 custom loci to the standard 550,000 loci on the HumanHap550 Genotyping BeadChip

ADDITIONAL INFORMATION

Please visit www.illumina.com

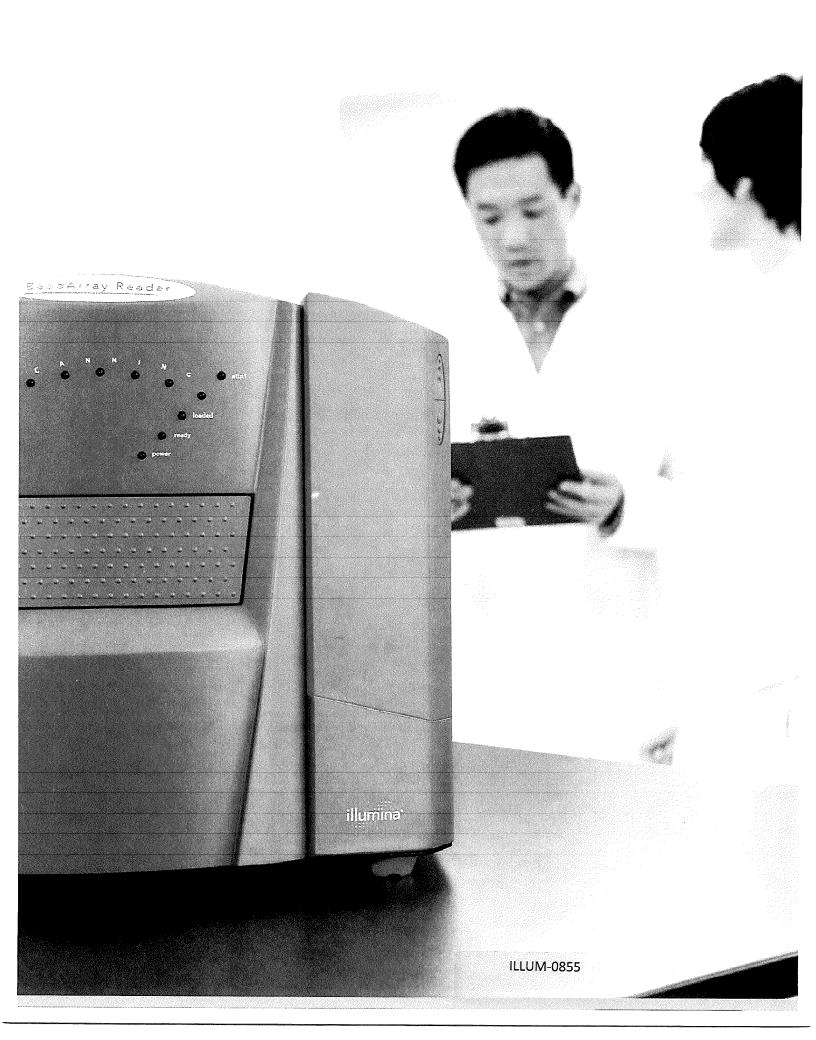
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ILLUM-0853

0853
raCode, and Making illumina\*







# GoldenGate® Indexing Assay Increases Sample Throughput

By combining sample indexing within the robust GoldenGate Assay, automation capabilities, and positive sample tracking with LIMS support, GoldenGate Indexing provides the highest level of throughput at the most affordable cost for low- to mid-plex custom genotyping screening.

Highlights

- Highest Throughput: Greater than 2,000 samples per day
- Highly Flexible: Advanced multiplexing enables analysis of 96, 192, or 384 loci per sample
- Fully Integrated:
  Automated platform incorporating LIMS
- Proven Technology:
   Robust assay used in genotyping centers worldwide with average call rates > 99%

#### Introduction

The GoldenGate Genotyping Assay is a highly successful genotyping technology proven in labs worldwide. In fact, it was used to make major contributions in the HapMap Project. Building on this strong foundation, the GoldenGate Indexing Assay allows researchers to pool multiple samples, increasing the number of samples that can be analyzed in a single run. With advanced automation and updates to Illumina LIMS (Laboratory Information Management System) to accommodate this new step, along with positive sample tracking, researchers now have the ability to screen up to 16 times as many samples per reaction as they could with the standard GoldenGate Assay. This dramatically increases throughput from 288 samples per day to greater than 2,000. Overall, researchers will realize a significant decrease in cost while maximizing throughput for low-complexity sample screening.

#### How GoldenGate Indexing works

GoldenGate Indexing, based on Illumina's BeadArray™ technology, maximizes the throughput of the original GoldenGate Assay (Figures 1 and 2). BeadArray technology uses illumiCodes, unique 23-bp single-stranded DNA oligos, to correctly identify each DNA sample as well as the loci being interrogated. Because each illumiCode is distinctive, multiplexing is possible. Current plexity ranges for GoldenGate Indexing include 96-plex, 192-plex, and 384-plex.

#### IllumiCodes Enable Pooling

During sample preparation, primers containing illumiCodes and universal primer sites are hybridized to the DNA. Individual samples can be processed using oligonucleotide assay pools containing non-overlapping illumiCodes. This enables pooling of multiple samples into a single

well. Since the illumiCodes are discreet within the well, each sample can be independently examined during downstream analysis.

#### **Amplification and Signal Reading**

Prepared samples are amplified using universal PCR primers labeled with Cy3 and Cy5 fluorescent dyes. The resulting fluorescently labeled PCR products are hybridized to a Universal BeadChip. The BeadChip contains randomly assembled universal beads, each displaying an illumiCode corresponding to a specific loci. DNA will bind to the bead containing the complementary illumiCode. Unbound DNA is removed and the remaining fluorescence signal levels read on the iScan system or BeadArray Reader for individual SNP genotype readout. This information is then analyzed for automated genotype clustering and calling. The entire assay can be completed in as few as three days.

#### Illumina LIMS and Automation Control

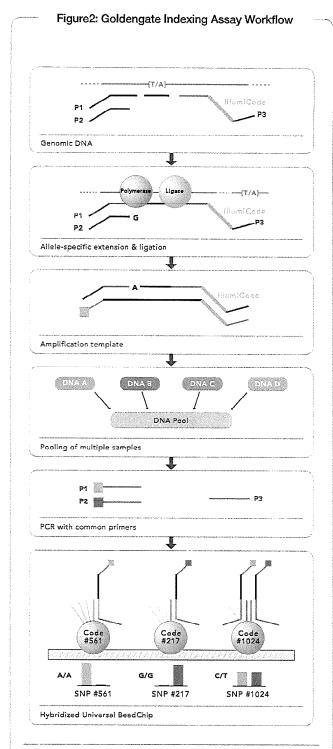
The GoldenGate Indexing assay is highly automated, maximizing throughput. Robotic liquid handlers automatically process samples through each step of the assay, enabling the assay to run with minimal hands-on operation. Pre-amplification steps are performed via a larger 96-tip-based robot, and post-amplification steps via a standard 8-tip robot.

Figure 1: Universal-32 beadchip



GoldenGate Indexing Assay products are hybridized onto the Universal-32 BeadChip for individual SNP genotype readout.

ILLUM-0856



In the GoldenGate Indexing assay, a unique set of illumiCodes is used to identify each sample, allowing multiple samples to be pooled prior to amplification. This, along with automation capabilities, greatly increases the assay throughput.

Illumina's integrated LIMS delivers state-of-the-art management and tracking to ensure the highest quality data, efficient data acquisition, and significant savings in time and lab resources. As a ready-to-use solution, Illumina LIMS includes the server hardware and software needed to accurately manage and enforce assay workflow. Illumina LIMS provides the excellent project management capabilities needed to effectively manage samples from receipt through analysis.

Positive sample tracking by Illumina LIMS is achieved by direct control of the automated liquid handling robots, ensuring samples are automatically processed and queued to the proper step and eliminating error due to manual mishandling. LIMS tracks time-stamped lab transactions with associated user information by offering user authentication either through Illumina LIMS or through existing Windows password authentication. In addition, LIMS uses a barcode system for accurate sample identification in downstream analysis. Illumina provides software updates to accommodate new product formats and workflows, saving the time and cost of in-house software development. By managing time-consuming and error-prone sample/data handling from beginning to end, the LIMS environment greatly increases confidence and efficiency in genotyping studies.

#### Reliable Analysis

GoldenGate Indexing Assay results can be analyzed in the genotyping module of GenomeStudio  $^{\text{TM}}$  data analysis software. This module recognizes each illumiCode and displays individual genotyping data for the pooled samples. In addition, GenomeStudio software features the ability to normalize raw data and perform clustering and automated genotyping calling.

#### **Data Quality**

GoldenGate Indexing Assays produce the same high-quality data as the original GoldenGate Assay. This ensures that important SNPs are captured and a high call accuracy is achieved (Table 1).

#### Summary

GoldenGate Indexing provides a fully automated, affordable assay for high-throughput low- to mid-plex genotype screening. Using a proven assay, researchers can now screen thousands of samples in just a few days, while still obtaining the high-quality data they require.

#### Additional Information

To learn how you can access the power of the GoldenGate Indexing Assay, visit www.illumina.com or contact us at the address below.

Figure 1: Specifications for the Goldengate Indexing Assay

Parameter	Specification	
Average Call Rate	> 99%	- nemero en
Reproducibility	> 99.9%	
Mendialian Inconsistencies	< 0.1%	

#### Data Sheet: SNP Genotyping

oduct	Plexity	No. of Samples Indexed	No. of Samples Processed per Kit	Catalog No.
GoldenGate Indexing Assay Kit, Custom	96	16	768	GT-222-1003
	192	8	768	GT-222-1004
	384	4	768	GT-222-1005

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owners. Pub. No. 370-2009-009 Current as of 29 July 2010

ILLUM-0858





### GPR VeraCode® Beads

VeraCode Universal Capture and Carboxyl Beads are now available as General Purpose Reagents (GPR) for rapid, convenient development of custom multiplex assays.

#### Highlights of GPR VeraCode Beads

#### Flexible Multiplex Assays:

Open platform enables development of cost-effective, custom assays for nucleic acid sequence or protein analysis.

#### · Progressive Licensing:

Product price includes rights for use in laboratory-developed tests or for resale of kits.

#### · High-Quality Platform:

Manufactured in a GMP environment.

#### • Verifiable Results:

Digital microbead codes provide unparalleled data quality whether paired with capture oligos or carboxyl molecules.

#### Introduction

For assay developers, access to flexible, high-quality, cost-effective multiplexing platforms for deploying new genomic and proteomic content is critical for success. Without it, incorporating newly validated information can be difficult. To overcome this challenge, Illumina offers VeraCode Universal Capture and Carboxyl Beads as General Purpose Reagents (GPR). These digitally coded microbeads enable development of custom multiplex assays in a variety of analysis methods, without the burden of royalty payments.

#### VeraCode Technology

Known for its versatility and reliability, the VeraCode platform leverages cutting-edge microbead technology to enable flexible multiplex assay deployment<sup>1</sup>. VeraCode microbeads are glass cylinders, each inscribed with a unique holographic code. This code enables positive identification for unparalleled data quality. Two different types of VeraCode beads are available. Universal Capture Beads allow custom design of nucleic acid–based assays, including allele-specific primer extension (ASPE) assays<sup>2</sup>. Carboxyl Beads provide an open platform for developing protein-based assays<sup>3</sup>.

## VeraCode Universal Capture Beads for Convenient, Flexible ASPE Assays

GPR VeraCode Universal Capture Beads, pre-coupled with 23-mer capture oligonucleotides, allow developers of custom multiplex assays to use their preferred assay methodology. Every capture sequence is paired with a specific bead type and pre-screened to limit cross reactivity within the human genome.

Multiple online design tools, such as primer 3 and mfold, are available for developing custom assays for use with Universal Capture Beads. Designed probes are attached to the Universal Capture Beads, which are then assayed. The use of solution-phase kinetics provides

a streamlined protocol and rapid sample processing. Single-plate chemistry minimizes hands-on time and reduces the chance of errors (Figure 1).

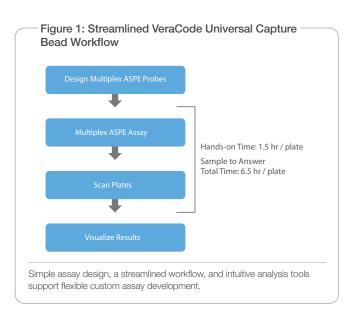
## VeraCode Carboxyl Beads Provide an Open Platform for Assay Development

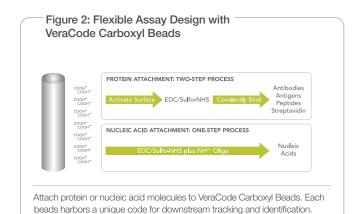
Carboxyl Beads enable covalent attachment of proteins, peptides, nucleic acid, and other ligands in a highly multiplexed format (Figure 2). These extremely stable beads demonstrate low non-specific binding, while the simple and flexible immobilization chemistry enables rapid assay design for a variety of analytes. Assay products can be labeled with standard fluorescent reporters such as phycoerythrin (R-PE), Cy3, Cy5, or Alexa Fluor dyes, providing an open platform for laboratory developed tests. Each assay bead type is present at high redundancy (30 bead types per sample average) to ensure high data quality.

#### Streamlined Workflow

Whether using Universal Capture or Carboxyl Beads, individual assay bead types can be pooled in combination for flexible multiplexing. Assays are conducted in 96-well plates to enable streamlined high-throughput workflows. The VeraCode Bead Kitting System reduces manual pipetting during distribution of custom bead pools into plates, reducing hands on time and the chance of user error. In addition, the highly stable VeraCode beads can be stored as kitted plates.

VeraScan and GenomeStudio® Data Analysis Software are available to support analysis for multiple applications, including nucleic acid and protein analysis.





**Progressive Licensing** 

Illumina has adopted a progressive licensing policy for General Purpose Reagents. GPR Universal Capture and Carboxyl Beads

include the rights for use in any manner consistent with a general purpose reagent, as defined by the US Food and Drug Administration, including use in a CLIA high-complexity laboratory for development of a laboratory-developed test and for use in kits intended for resale. No subsequent royalty payments are required.

#### **Additional Information**

To learn more about VeraCode technology, visit www.illumina.com. For information about collaborating with Illumina for the development of kits for resale using Universal Capture or Carboxyl Beads or other Illumina technologies, please contact Marla Bornstein at marlabornstein@illumina.com.

#### References

- 1. www.illumina.com/downloads/VeraCodeBrochure.pdf
- 2. www.illumina.com/downloads/UniversalBeadSts\_DataSheet.pdf
- 3. www.illumina.com/downloads/CarboxylBeadSts\_DataSheet.pdf

roduct	Quantity	Catalog No.
GPR VeraCode Universal Capture Bead Sets*		
GPR VeraCode Universal Bead Set, Code 5440	6 × 96 reactions	VC-910-5440
GPR VeraCode Universal Bead Set, Code 5632	6 × 96 reactions	VC-910-5632
GPR VeraCode Universal Bead Set, Code 5634	6 × 96 reactions	VC-910-5634
Pre-pooled GPR VeraCode Universal Capture Bead Set with 48 unique bead codes per vial	6 × 96 reactions	VC-910-0481
Pre-pooled GPR VeraCode Universal Capture Bead Set with 48 unique bead codes per vial	6 × 96 reactions	VC-910-0482
GPR VeraCode Carboxyl Bead Sets		
GPR VeraCode Carboxyl Bead Set A	6 × 96 reactions	VC-920-8193
GPR VeraCode Carboxyl Bead Set B	6 × 96 reactions	VC-920-8199
GPR VeraCode Carboxyl Bead Set C	6 × 96 reactions	VC-920-8208
GPR VeraCode Carboxyl Bead Set D	6 × 96 reactions	VC-920-8214
GPR VeraCode Carboxyl Bead Set E	6 × 96 reactions	VC-920-8226
GPR VeraCode Carboxyl Bead Set F	6 × 96 reactions	VC-920-8240
GPR VeraCode Carboxyl Bead Set G	6 × 96 reactions	VC-920-8258
GPR VeraCode Carboxyl Bead Set H	6 × 96 reactions	VC-920-8265
GPR VeraCode Carboxyl Bead Set I	6 × 96 reactions	VC-920-8288
GPR VeraCode Carboxyl Bead Set J	6 × 96 reactions	VC-920-8322

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